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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,903	01/11/2002	David Michael Goldstein	R0038G-DIV	4961

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[REDACTED] EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/045,903	GOLDSTEIN ET AL.	
	<b>Examiner</b> Laura L. Stockton, Ph.D.	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 March 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2-16,22-31,33-35 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 2-16, 22-31, 33-35 and 38-41 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

## **DETAILED ACTION**

**Claims 2-16, 22-31, 33-35 and 38-41 are pending in the application.**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 4, 2003 has been entered.

### ***Claim Objections***

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved

throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 36-39 been renumbered claims 38-41,  
respectively.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C.  
112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-16, 22-31, 33-35 and 38-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey

to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have added subject matter in claims 2, 33 and 41 which does not have support in the specification or the originally filed claims. See, specifically, the definition (o) of R<sup>3</sup> in claim 2, the (v) and (w) definitions of R<sup>3</sup> in claim 33, and the (v) definition of R<sup>3</sup> in claim 41. Applicants state that support is found on pages 57, 59 and 72 of the specification. However, this showing is not persuasive. Enablement for a single compound cannot provide enablement for the breadth of claims sought in arts which are unpredictable. *Ex parte Hitzeman*, 9 USPQ2d 1821 (BPAI 1987). Therefore, the claims lack written description as such.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-6, 16, 22-24, 33-35 and 38-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-21 of U.S. Patent No. 6,376,527. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims in the patent differ only by generic description of the pyrazole product used in the method.

See, for example, the patent's claim 19 wherein R<sup>1</sup> is hydrogen, R<sup>2</sup> is hydrogen, A and B are each aryl, R<sup>3</sup> is heteroalkoxy, R<sup>4</sup>, R<sup>5</sup> and R<sup>6</sup> are

each hydrogen. One skilled in the art would thus be motivated to prepare pyrazole products embraced by the patent to arrive at the pyrazole products found in the instant claims with the expectation that the obtained pyrazole products would be useful in treating inflammatory disorders such as arthritis. Therefore, the instant claimed method of using the pyrazole products would have been suggested to one skilled in the art.

### *Response to Arguments*

Applicants indicated that a terminal disclaimer would be filed when all outstanding issues are resolved.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-7, 12, 16, 22-24, 33-35 and 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faraci et al. {WO 94/13643}.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Applicants claim a method of treating a disease in a mammal treatable by administration of a p38 MAP kinase inhibitor (such as inflammation disorders) by administering pyrazole products.

Faraci et al. teach pharmaceutically active pyrazole products, that are structurally similar to the instant pyrazole products, that are administered in the instant claimed method. See in Faraci et al. (pages 1 and 2), for example, wherein A is  $-C(=O)$ ,  $R_1$  is amino,  $R_2$  is alkyl,  $R_3$  is phenyl substituted with hydroxy-alkyl and  $R_4$  is phenyl. Also see, for example, the products on page 31, lines 5 and 12; page 39, line 11; and page 44, lines 12-14. Faraci et al. teach the pyrazole products are useful in treating disorders such as inflammatory disorders and immune suppression (page 5, lines 1-12).

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the teaching in the prior art and the invention instantly claimed is that of generic description of the pyrazole products being administered for the intended use.

*Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)*

The motivation to make the pyrazole products derives from the expectation that structurally similar compounds would possess similar activity (e.g., an anti-inflammatory).

One skilled in the art would thus be motivated to prepare pyrazole products embraced by Faraci et al. to arrive at the pyrazole products found in the instant claims with the expectation that the obtained pyrazole products would be useful in treating inflammatory disorders such as arthritis. The instant claimed method of using the pyrazole products would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

*Response to Arguments*

Applicants' arguments filed March 4, 2003 have been fully considered. Applicants argue that the preamble in the claims imparts life and meaning to the claims which should be considered in analyzing patentability. Applicants argue that Faraci et al. do not teach treating a disease in a mammal treatable by administration of a p38 kinase inhibitor as is instantly claimed. Applicants argue that the specie found in Faraci et al. have a methylthio group at the 3-position of the pyrazole ring but the instant claimed products do not have a methylthio group at the 3-position of the pyrazole ring (the instant R<sup>2</sup> variable). Applicants further argue that one skilled in the art would not have been directed to the instant claimed invention.

All of Applicants' arguments have been considered but have not been found persuasive. Applicants claim a method of treating diseases by administering a p38 inhibitor. In Applicants' specification on page 35, lines 3-8, diseases which can be treated using a p38 inhibitor are disclosed. Inflammatory diseases, as taught by Faraci et al., as well as

Alzheimer's disease are embraced by Applicants' claims. Further, a compound and its properties are inseparable. *In re Papesch*, 137 USPQ 43 (CCPA 1963).

Additionally, it is well-established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art to person of ordinary skill in the art. *In re Boe*, 148 USPQ 507, 510 (CCPA 1966).

The difference between the methods of Faraci et al. and the methods instantly claimed is that some of the methods utilize products which are generically embraced by the products of Faraci et al. Faraci et al. prepare specie which differ only at one position from the products instantly claimed or otherwise, the rejection of the claims would have been made under 35 USC § 102(b). Faraci et al. also teach that R<sup>2</sup> representing "ethyl" is a preferred embodiment (page 4, line 6). Applicants teach that their R<sup>2</sup> variable can be an alkyl group.

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating inflammatory disorders. Therefore, the instant claimed invention would have been obvious to one skilled in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

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The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.



Laura L. Stockton, Ph.D.  
Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600

**June 16, 2003**